THE Cicala Law Firm PLLC

April 11, 2024

Via ECF

Honorable Brian R. Martinotti
United States District Court
District of New Jersey
Frank Lautenberg Post Office & U.S. Courthouse
2 Federal Plaza, 3rd Floor
Newark, New Jersey 07102

Honorable Rukhsanah L. Singh
United States District Court
District of New Jersey
Clarkson S. Fisher Fed Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *In re Insulin Pricing Litigation*, Case No. 2:23-md-3080 (BRM/RLS)

Dear Judges Martinotti and Singh:

We write on behalf of the State Attorney General Track to oppose the Manufacturers' request to file a Rule 12(c) motion for partial judgment on the pleadings in *The State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly and Company, et al* ("Mississippi case"). For the foregoing reasons, the proposed motion should be denied.

I. The GLP-1 Drugs Are Unlawfully Priced Because of the Same Unlawful Scheme as Insulin and Defendants Never Challenged Their Inclusion

The GLP-1 drugs are part of the same unlawful pricing scheme as the insulin products. Accordingly, they are included within the scope of drugs in most, if not all, of the complaints in the MDL and have been from the start—beginning with the Mississippi case filed nearly three years ago in June 2021.[1] And in the Mississippi complaint, as well as in every State AG case filed thereafter, the allegations have remained the same, that the Defendants engaged in deceptive and unfair conduct with respect to all of the at-issue diabetes medications, including the GLP-1 drugs.[2]

The price of insulin has skyrocketed more than 1,000% during the relevant time period, with current prices having no relationship to the prices realized by Defendants. The GLP-1 drugs suffer from the same abusive pricing scheme as a result of the same conditions. Indeed, just two weeks ago, the Journal of American Medicine published a study that found that insulins, as well as other diabetes drugs, including GLP-1s, could be profitably priced far below current prices and such practices would enable significant expansion of diabetic treatment."[3]

Although the GLP-1 drugs have been included in the State AG cases from the start not a single one of the Defendants' *five* fully briefed 12(b)(6) motions challenged the inclusion of the

[1] The Manufacturers of course have always been well aware of this; their own Rule 12(b) motions in the each of the State AG cases describe the claims as involving the prices of "diabetes medications." *See, e.g.*, Dkt. 39 at 7.
[2] *See, e.g.,* Mississippi case Compl. at Table 1 (listing the at-issue drugs, including GLP-1s); Fig. 10 (showing GLP-1 lockstep price increases). The bulk of the allegations in the Mississippi complaint lay out the Defendants' illegal pricing scheme which, as detailed in the Complaint, apply to all of the at-issue drugs, including the GLP-1s.
[3] *See* "Estimated Sustainable Cost-Based Prices for Diabetes Medicines," available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2816824

GLP-1s, nor did any of these motions raise any patent-based or preemption defenses. In other words, the Defendants are now asking for a sixth bite at the apple to assert new arguments they failed to raise the first five times they had the chance to do so. The Court should deny this request.

Moreover, discovery has been underway in the State AG cases for over two years and it involved all at-issue drugs, including the GLP-1s. The ESI Protocols entered in the State AG cases before transfer to the MDL expressly identified the GLP-1s as relevant at-issue drugs that the parties could not redact.[4] More than 277,000 documents produced in the Mississippi case relate directly to the GLP-1s. The Manufacturers have always understood those documents to be relevant, did not redact information relating to GLP-1s, and have never brought up any issue related to GLP-1s in this MDL—not in their proposal for addressing motions to dismiss, not in their draft discovery plan, and not during any of the related meet-and-confers. Claiming, as the Manufacturers do in their letter to this Court, that including the GLP-1s in discovery in this MDL will result in beginning "anew" is an assertion totally belied by the facts. To the contrary, GLP-1 discovery was already well underway and should continue here.

Because the underlying conduct derives from similar facts, there is substantial overlap with respect to Plaintiffs' discovery related to the unlawful pricing of both types of products. Any suggestion that the GLP-1s are beyond the scope of this MDL is baseless.[5] Litigation efficiency demands that both types of products be included at this stage of the case.

II. A Motion for Partial Judgment on the Pleadings is Inappropriate and Untimely

As detailed above, the facts do not support the Manufacturers' request. But neither does the Rule 12(c) legal standard. A Rule 12(c) motion is not appropriate unless the movants can establish that no material issue of fact remains to be resolved. *See Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). Defendants cannot meet this burden.

For example, the State of Mississippi alleged that the Manufacturers published list prices for all at-issue drugs—including the GLP-1s—knowing that they were untethered from the actual prices and knowing that these prices were used to set the prices paid by diabetics. The State further alleges that the Manufacturers steep price increases occurred in lockstep and caused substantial harm. Manufacturers' proposed motion cannot succeed because there are material issues of fact remaining to be resolved. *Rosenau*, 539 F.3d at 221.

Further, the Mississippi court has already denied the Manufacturers' 12(b)(6) motion, finding that the State's claims, which include the GLP-1s, were adequately pled.[6] While the Manufacturers now assert that the State's factual allegations do not pertain to GLP-1s, as described above the deceptive and unfair pricing scheme alleged in the State's complaint unquestionably includes the GLP-1s. The fact that some of the GLP-1s were launched more recently is immaterial;

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[4] *See, e.g.*, Dkt. 175, Stipulated Protocol for the Discovery of Electronically Stored Information and Hard Copy Documents, *Mississippi v. Eli Lilly Co.*, No. 3:21-cv-00674-KHJ-MTP (S.D. Miss. Feb. 16, 2023).

[5] The JPML transfer order recognizes that this litigation concerns "the price of insulin and other diabetes medications," identifies common questions of fact regarding the scheme to "fraudulently inflate the price of insulin ***and other diabetes medications***." Dkt. 91 at 1, 3-4.

[6] *Mississippi v. Eli Lilly Co.*, No. 3:21-cv-00674-KHJ-MTP, Dkt. 111 (S.D. Miss. Aug. 9, 2022)

the Manufacturers have included them in the ongoing and pre-existing pricing scheme that the States allege. Furthermore, this Court previously considered the same argument by Manufacturers in the consumer class action and found it "unconvincing." [7]

Moreover, Rule 12(c) motions "should be made promptly after the close of the pleadings." Wright & Miller, 5C Fed. Prac. & Proc. Civ. § 1367 (3d ed.). While a later motion may be permitted where it "may effectively dispose of the case on the pleadings," "if the pleadings do not resolve all of the factual issues in the case, proceeding with discovery and potentially a trial on the merits would be more appropriate than an attempt at resolution of the case on a Rule 12(c) motion." *Id.* In the Mississippi case, the pleadings closed in September 2022. The action was pending in the district court for nearly a year before being transferred to this Court, and discovery was well under way—discovery that indisputably included the GLP-1 drugs. The time for a 12(c) motion has long since passed, and proceeding with discovery is the more appropriate course, particularly since the proposed motion would not dispose of the case.

III. The Manufacturers' Preemption Arguments are Unlikely to Succeed

Finally, not only is the Manufacturers' proposed motion factually flawed and procedurally improper, but it should also fail on the merits. Mississippi's claims related to GLP-1s are not preempted under federal patent law. The Manufacturers rely on two cases to support their preemption theory. But multiple federal courts have held the opposite—that federal patent law does not preempt consumer protection claims when those claims address different wrongs. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litigation*, 336 F. Supp. 3d 1256, 1334 (D. Kan. 2018); *see also In re DDAVP Indirect Purchaser Antitrust Litigation*, 903 F. Supp. 2d 198, 217 (S.D.N.Y. 2012) (no patent preemption for consumer protection claims); *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307, 356-57 (D.R.I. 2017) (state law claims not preempted by federal patent law); *Picone v. Shire PLC*, 2017 WL 4873506, at *14 (D. Mass. Oct. 20, 2017) (tortious conduct in the marketplace is not protected or governed by federal patent law). Here, Mississippi's state law claims are premised on the Manufacturers' unfair and deceptive actions, and federal patent law does not relate to nor shield them from this wrongdoing.

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The Mississippi case has been on file for nearly three years and the pleadings have been closed for over a year and half. Yet, in all that time the Defendants have never asserted that the GLP-1 drugs should not be a part of this case. Despite the pretextual arguments raised in their letter, the reasons are clear why the Manufacturers now want these drugs out. The GLP-1s have become blockbuster drugs (Ozempic netted Novo Nordisk over $15 billion in revenue last year alone) and the Manufacturers have come under heavy fire recently for the harm caused by their egregious price increases.[8] None of that, however, changes the fact that the Defendants already challenged the sufficiency of the Mississippi complaint and lost. The Court should deny the Defendants request to revisit that ruling and discovery should be allowed to move forward with respect to all of the at-issue drugs, including the GLP-1s.

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[7] *In re Insulin Pricing Litig.*, Case No. 3:17-cv-699, Dkt. 304 at 7-8 (D.N.J. Feb. 20, 2020).

[8] https://fortune.com/europe/2024/03/28/ozempic-maker-novo-nordisk-facing-pressure-as-study-finds-1000-appetite-suppressant-can-be-made-for-just-5/; https://www.theguardian.com/global-development/2024/mar/28/drug-companies-diabetes-drugs-medicines-ozempic-trulicity ([GLP-1s] are an absolute gamechanger for people living with diabetes, but are kept out of the hands of hundreds of millions of people . . .").

THE Cicala Law Firm PLLC

Respectfully submitted,

Joanne M. Cicala
THE CICALA LAW FIRM PLLC
101 College Street
Dripping Springs, Texas 78620
Tel. (512) 275-6550
joanne@cicalapllc.com

W. Lawrence Deas
LISTON DEAS PLLC
Post Office Box 14127
Jackson, Mississippi 39236
Tel. (601) 981-1636
william@listondeas.com

Walter G. Watkins
FORMAN WATKINS & KRUTZ LLP
210 East Capitol Street, Suite 2200
Jackson, Mississippi 39201-2375
Tel. (601) 960-8600
trey@formanwatkins.com

Co-Leads for the State AG Plaintiffs

cc: All Counsel of Record (via ECF)